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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/779,767	01/07/97	ZAGHOUANI H	ALLIA.143A

18M1/0801

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EXAMINER	
REEVES, J	
ART UNIT	**PAPER NUMBER**
1806	

DATE MAILED: 08/01/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 08/779,767	Applicant(s) Zaghouani
	Examiner Julie E. Reeves, Ph.D.	Group Art Unit 1806

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *zero* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-65* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-65* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ SB6 PTO 948

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 22-29, drawn to an Fc receptor ligand and immunosuppressive factor fusion, classified in class 514, subclass 12.

II. Claims 12-21, drawn to a recombinant method of making an immunomodulating agent for endocytic presentation, classified in class 435, subclass 69.6.

III. Claims 30-38, drawn to a method of making a pharmaceutical compound, classified in class 424, subclass 182.3.

IV. Claims 39-48, drawn to a method of treating a patient by administering an immunomodulating compound, classified in class 424, subclass 182.1.

V. Claims 49-54 and 55-60, drawn to the polynucleotides encoding a Fc receptor ligand and an immunosuppressive factor and host cells transformed with the polynucleotides, classified in class 536, subclass 23.4.

VI. Claims 61-65, drawn to an in vitro method of endocytic presentation, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and Inventions V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions recite different compounds that have different effects and different modes of operation. Invention I recites a polyprotein while invention V recites a polynucleotide sequence. The polyprotein cannot be used for a method of expression and the polynucleotide cannot be used for a method of immunization. Thus inventions I and V are patentably distinct.

3. Inventions I and Inventions III, IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide product can be used for in vivo and in vitro methods as evidenced by Inventions IV and VI in addition to a method of making a pharmaceutical compound, as recited in Invention III.

4. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of invention I can be made by a materially different process of biochemical synthesis and fusion in addition to the recombinant method recited in Invention II.

5. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects. Invention IV recites a method of treating an immune response while Invention VI recites an in vitro assay.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Species A: proteolytic protein

b. Species B: myelin basic protein.

These species are patentably distinct because proteolytic protein and myelin basic protein have a different epitope profile and different protein stability due to the differences in their primary amino acid sequences. Immunization with either results in a different panel of cross reactive proteins.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 6-13, 16-23, 26-31, 34-40, 43-65 are generic.

9. This application contains claims directed to the following patentably distinct species of the claimed invention: If Invention IV is chosen, then an election is needed between the following autoimmune disorders

a. Species C: multiple sclerosis

b. Species D: lupis.

c. Species F: rheumatoid arthritis

d. Species G: scleroderma

e. Species H: insulin dependent diabetes

f. Species I: ulcerative colitis

These species are patentably distinct because each disorder has a different effected organ, etiology process and a different mode of diagnosis and treatment, and prognosis due to the different mechanisms of pathology of the various disorders.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 39-48 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

g. A telephone call was made to Ned Isrealsen on 23 July 1997 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Reeves, Ph.D., whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

11. Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**lila.feisee@uspto.gov**].

12. All Internet e-mail communications will be made of record in the application file. **PTO**

employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

13. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Julie E. Reeves, Ph.D.

(703) 308-7553

SHEELA HUFF
PATENT EXAMINER
GROUP 1800